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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/535,243

12/20/2005

Ghisalberti Carlo

MARGI-0044

5778

23599

7590

03/04/2008

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EXAMINER

WESTERBERG, NISSA M

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

03/04/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/535,243	Applicant(s) CARLO, GHISALBERTI	
	Examiner Nissa M. Westerberg	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 - 19 is/are pending in the application.
- 4a) Of the above claim(s) 8 - 10, 15, 17 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 - 7, 11 - 14, 16, 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/5/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group II (claims 11 – 14) and deferiprone as the hydroxypyridonone in the replies filed on November 9, 2007 and January 2, 2008 is acknowledged. The traversal is on the ground(s) that unity of invention exists and searching all the claims would not be an undue burden. As all the claims have been amended to recite methods of treating a skin microcirculatory disorder, the restriction requirement is withdrawn. The traversal argument is not found persuasive because searching the various chemical structures would require different search queries and the prior art applicable to one invention would not likely be applicable to another invention.

The species election requirement is still deemed proper and is therefore made FINAL.

Status of Claims

Claims 1 – 19 are pending. Claims 8 – 10, 15, 17 and 18 are withdrawn as not being drawn to the elected invention. Claims 1 – 7, 11 – 14, 16 and 19 are currently under examination.

Comments and Notes

The structures of formulae I – III are blurry in amended claims 1 and 11. Identification of the superscript numbers in the R groups is difficult and the specification or original claims must be consulted for unambiguous identification of the superscript numbers. It is kindly requested that Applicant's submit an amended set of claims in which all features of formulae I – III are shown clearly.

Specification

2. The disclosure is objected to because of the following informalities: the title of the application contains a misspelling. The title contains the word "microcirculatroy" which should be "microcirculatory".

Appropriate correction is required.

Claim Objections

3. Claim 13 is objected to because of the following informalities: claims can only depend from previous claims and claim 13 refers to subsequent claim 14. Appropriate correction is required.

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4. Claim 19 is objected to because of the following informalities: the compound 1-methyl-2-ethyl-3-hydroxy-4-pyridinone is listed twice. Appropriate correction is required.

Claim Rejections - 35 USC § 112 2nd Paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 14 refers to claim 14 and contains no steps in the method of treating. Claim 13 depends from 14 and suffers from the same lack of steps in the method of treating.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 7, 11, 14, 16 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Ghisalberti (WO 01/17497, cited on PTO-1449).

Ghisalberti discloses the treatment of human patients with red pigmentary spots after sclerotherapy (p 25, example 2). These patients had spots that were hemosiderinic in nature which means they arise from bleeding. These patients were treated with a gel (admixture, gel (B)) comprising deferiprone and the dermatologically and cosmetically acceptable carriers xanthan gum and distilled water. These compositions were only applied locally to the spots to be treated. The application of the compositions was also topical since the compositions were applied to the skin.

For the rejection of claim 14, it has been assumed that this claim depends from claim 11, providing the composition that is used in the method of treatment of the disorders listed in claim 14.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

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3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1 – 7, 11-14, 16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ghisalberti (“497 above) in view of Murad (US Patent 6,630,163).

Ghisalberti teaches compositions which are useful for the treatment of hyperpigmented skin (p 1, ln 6 – 8). Hyperpigmentation of the skin can result from increased melanin, but also the presence of other pigments such as hemosiderin that is present in the patients who were treated with deferiprone after undergoing sclerotherapy (p 25, ln 21). Ghisalberti does not disclose the use of these compounds for treating other skin conditions such as rosacea or purpura.

Murad discloses a dermatological agent that comprises a fruit extract (col 7, ln 42 – 43) that can be administered for the management of dermatological conditions (col 7, ln 45 – 49). Included in the list of dermatological conditions that may be treated or

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modified using this method are senile purpura (col 8, ln 5), rosacea (col 8, ln 7) and hyperpigmentation (col 8, ln 9).

Purpura is a generic name for the discoloration of the skin caused by bleeding from small blood vessels that have a variety of causes (p 1, DermnetNZ entry for “purpura”, accessed 2/19/2008). One type of purpura, pigmented purpura, is also known as capillaritis (p 1, DermnetNZ entry for “capillaritis”, accessed 2/19/2008). As disclosed in the instant specification, capillaritis encompasses a variety of conditions, including several types of purpura (Schamberg’s disease, purpura annularis telangiectodes, itching purpura and pigmented purpuric lichenoid dermatosis) and lichen aureus (p 6, ln 15 – 20). Cutaneous vasculitis refers to an inflammation of blood vessels in the skin (p 1, DermnetNZ entry for “cutaneous vasculitis”, accessed 2/19/2008) that, in its acute stage, presents with bleeding under the skin (purpura; p 3). Rosacea is a disease that is characterized by blotchy red areas of the skin that results from vessel leakage (p 1, ln 19 – 22 of the instant specification). All of these conditions are characterized by the presence of blood outside the blood vessels.

The red pigmentary spots after sclerotherapy treated by Ghisalberti using deferiprone are the result of blood within the skin but outside the blood vessels. One of ordinary skill in the art would have a reasonable expectation of success in using deferiprone, shown by Ghisalberti to be effective for the treatment of hemosiderinic spots after sclerotherapy, on other conditions such as purpura or cutaneous vasculitis in which blood is present in the skin but is not contained within the blood vessels. The combined teachings of Ghisalberti and Murad renders obvious the use of deferiprone

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and a cosmetically or pharmaceutically acceptable carrier for the treatment of purpuras, rosacea, cutaneous vasculitis and skin capillaritis to one of ordinary skill in the art at the time of the instant invention.

Conclusion

Claims 1 – 7, 11 – 14, 16 and 19 are rejected. Claims 13 and 19 are objected to. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 7:30 a.m. - 5 p.m. ET. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NMW

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618